EXAMINER'S AMENDMENT

1.   An examiner's amendment to the record appears below. Should the changes

and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be

submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview

with Ted Whitlock on January 18, 2012.

2.   The application has been amended as follows:

- Claims 43-45 should be dependent on claim 34, and not 44.

    a. Claim 43 (new). A pharmaceutical tablet as defined in claim ~~44~~ **34** in which said

       drug is warfarin.

    b. Claim 44 (new). A pharmaceutical tablet as defined in claim ~~44~~ **34** in which said

       drug is digoxin.

    c. Claim 45 (new). A pharmaceutical tablet as defined in claim ~~44~~ **34** in which said

       drug is levothyroxine.

- Claims 48-50 should be amended as follows:

    d. Claim 48 (new). A method of breaking a pharmaceutical tablet as defined in claim

       34 wherein said tablet is broken by applying force to said ~~first and said second~~

       ~~unitary segments~~ **top inactive non-unitary segment** to cause the tablet to break

       through said first segment.

    e. Claim 49 (new). A method of breaking a tablet as in claim 48 that comprises first

       breaking said tablet through said ~~first segment~~ **top inactive non-unitary**

segment to obtain a tablette that contains part of said first segment plus unitary

segments and thereafter breaking said tablet between said first and said second

unitary segments so that the tablet breaks substantially completely within said

first segment.

    f.   Claim 50 (new). A method of administering a partial dose of a drug contained in

a pharmaceutical tablet, said method comprising breaking a pharmaceutical

tablet according to claim 34 by breaking said tablet through said ~~first segment~~

top inactive non-unitary segment to form two or more tablettes each

containing a unitary segment and having a patient, other person, or other animal

in need thereof ingest a tablette containing a unitary segment.

Reasons for Allowance

3.   The following is an examiner's statement of reasons for allowance:

  i.   Applicant presented new claims 34-51 which further clarify the arrangement of

the compressed, layered pharmaceutical tablet with respect to: the embossed

bottom tablet punch, the first and second unitary segments containing the active

ingredient, the tamping of the bottom layer (containing the unitary segments), the

top non-unitary inactive segment, and the breaking of the tablet through the top

non-unitary segment.

  ii.   Applicant's arguments (see Pages 6-14, filed 01/09/12) regarding the distinction

of the instant invention from the closest prior art reference Hess et al. (CH

648754 – "Hess") were found persuasive. Hess does not teach an embossed

bottom tablet punch and a top tablet punch that is not embossed. Hess does not

teach tamping of an active-containing layer that has a level top surface on which

an inactive non-unitary segment is deposited. Hess does not teach breaking the

tablet through the top inactive non-unitary segment.

iii.   The declaration under 37 CFR 1.132 by Dr. David P. Beach (filed 01/09/12) has

been fully considered and was persuasive. The declarant states that the process

of manufacturing the tablets according to Hess is carried out without a tamping

step applied to the first layer, and that without tamping the first layer before

depositing the second composition, the first layer will not have a uniform (or

level) surface to interface with the second composition. The declarant provided a

comparison of a bi-layer tablet with an embossed upper (top) punch (FIG. 1) and

a bi-layer tablet scored with embossed lower (bottom) punch (FIG. 2 – instant

invention) which shows that when an embossed bottom tablet punch is used, a

straight-line, planar interface of the layers results, and there is no "push effect" or

mingling of the active layer into the inactive layer, or vice versa.

iv.   A further prior art search did not disclose a reference that teaches the specific

arrangement of the compressed, layered pharmaceutical tablet as recited in

instant claims.

Therefore, the claimed invention is novel and unobvious over the prior art of

record.

Comments

4.   Any comments considered necessary by applicant must be submitted no later

than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

5.   Claims **34-51** are allowed.

6.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aradhana Sasan/   /Robert A. Wax/
Examiner, Art Unit 1615   Supervisory Patent Examiner
                                       Art Unit 1615